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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B | A2

(11) International Publication Number: WO 98/35606

(43) International Publication Date: 20 August 1998 (20.08.98)

(21) International Application Number: PCT/US98/03069

(22) International Filing Date: 13 February 1998 (13.02.98)

(30) Priority Data:
60/038,380 13 February 1997 (13.02.97) US

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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

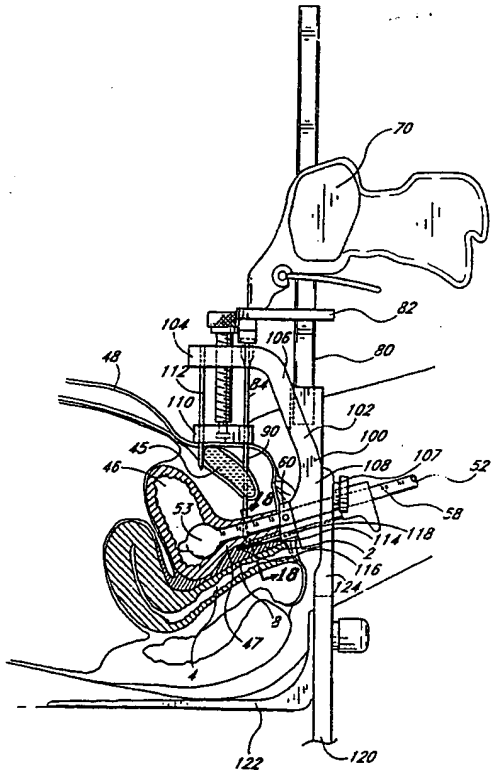
Published

Without international search report and to be republished upon receipt of that report.

(54) Title: METHOD AND APPARATUS FOR MINIMALLY INVASIVE PELVIC SURGERY

(57) Abstract

The invention provides a driver (70) and methods for advancing needles, cannulas (90), and other medical devices through the pubic bone (45). The driver (70) may be used in connection with a driver frame assembly (100) for proper positioning and stabilization of the driver (70), and with other devices for creating a cavity in the urethral floor and for positioning medical devices therein. The invention also provides simple connections (126) for attaching a suture (88) to a device within the cavity in the urethral floor or in the vagina (4), and also for attaching sutures (88) to the pubic bone (45).



METHOD AND APPARATUS FOR MINIMALLY INVASIVE PELVIC SURGERY

Field of the Invention

The present invention relates to methods and devices for improving urinary incontinence. More particularly, the present invention relates to methods and devices for creating a cavity near the urethral floor, methods and devices for placement of a urethral sling or other device in such a cavity, and methods and devices for driving bone-piercing guides into and through the pubic bone for use in stabilizing the urethral or pelvic floor.

Background of the Invention

The present invention relates to the treatment of stress urinary incontinence "SUI," and to improved methods and surgical devices for the surgical treatment of SUI. The devices disclosed herein are additionally useful in a wide variety of other surgical procedures.

Genuine stress incontinence is the involuntary loss of urine due to a sudden rise in intra-abdominal pressure. It has been estimated that between 40% and 50% of young, healthy nulliparous women admit to occasional mild stress incontinence; however, at least 80% of stress incontinence patients are in the perimenopausal age group and are multiparous. Raz has suggested that the female urethral continence mechanism is dependent on the interaction of four urethral factors: urethral closing pressure, urethral length, urethrotrigonal anatomy, and urethral reception of intra-abdominal pressure. Raz, S., Modified bladder neck suspension for female stress incontinence, Urology, 17:82, 1981.

The urethral closing pressure is predominantly a result of the interaction of smooth and striated muscle sphincter activity, but there is also some contribution by nonmuscular urethral factors such as the submucosal vascular plexus, the elastin and collagen content of the urethral tissues, and a sphincter like effect of the mucosa. There has been considerable diversity of opinion regarding the anatomic structure and the innervation of the urethral sphincters, and a variety of views have been expressed in the literature.

Urethral length is important in the maintenance of continence. However, although it certainly interacts with other factors to contribute to continence, a short urethra alone will not produce incontinence. Urethral length varies considerably in normal women, and women with proven genuine stress urinary incontinence do not invariably have urethral shortening.

Urethrotrigonal anatomy, which can be demonstrated by lateral cystourethrography, should fulfill certain criteria. The bladder base should lie above the level of the inferior ramus of the symphysis, and with straining should not descend more than 1.5 cm. There should be a normal urethrotrigonal alignment with an angle normally less than 100 degrees, and the urethral axis should be approximately 35 degrees from the vertical. In the hypermobile situation loss of all of the normal anatomic features may occur, a radiologic finding that correlates with the clinical finding of cystourethrocele. However, clinical experience has shown that the coexistence of cystourethrocele and incontinence does not predict that the incontinence is of a genuine stress variety.

This invention also seeks to provide alternatives to transvaginal methods of urethral and pelvic floor reconstruction and stabilization, to minimize the risk of infection, and to enable surgeons to approach the urethral or pelvic floor from different locations. Finally, it is a further objective to provide minimally invasive means and methods of securing a target tissue to an immoveable reference tissue, such as the pubic bone. One of more of these objectives is satisfied by various embodiments of the invention.

The invention provides a dilator for creating a cavity in tissue. The dilator has two functional portions: an insertion spreader and handles. The insertion spreader includes of two facing guides that may be semi-cylindrical. The spreader has open and closed positions. In the closed position the guides are close together and the dilator may have the appearance of a split tube or cylinder, while in the open position the guides are separated. In both positions the guides remain essentially parallel to each other.

The insertion spreader may be attached to the handles for manipulation of the guides. The handles can be joined together with a pivot, so that pivoting the handles translates to a movement of the guides either toward or away from one another. The dilator may also have a ratcheting lock for maintaining the insertion spreader in a fixed position. The penetrating ends of the guides also may be sharpened to facilitate penetrating the target tissue.

The dilator aspect of the invention also provides a method of creating a tissue cavity by using the dilator. With the insertion spreader in the closed position the spreader is advanced into the target tissue. When the spreader reaches the desired depth the handles are moved to separate the guides. The separation of the guides causes a tearing of the tissue, creating a cavity therein. This method also may be employed by first advancing a needle partially into the tissue to create an insertion path. The guides of the spreader are positioned about the protruding part of the needle and inserted into the tissue along the same path created by the needle.

This method for spreading tissue with the dilator of the invention may be used to create a cavity in the vaginal hiatus. The term "vaginal hiatus" refers to the tissue between the urethra and the vagina. This term may apply to the exterior surface between the distal urethra and the vaginal orifice as well as to the deeper tissue between the urethra and the upper vaginal wall. In some cases spreading may be facilitated by performing an episiotomy of the skin of the vaginal hiatus. The method of this aspect of the invention also may be performed transvaginally to create a cavity, for example in the vaginal wall. Whatever the tissue, the method may be preceded with a fluid-dissection of the target tissue, wherein a solution is injected into the tissue to create a fluid bolus. The fluid bolus forms a pocket in the tissue, and the dilator is used to create an opening connecting the outer surface to the pocket.

The invention also provides an insert card for advancing a medical device, for example a urethral sling, into a tissue cavity. One end of the card holds the sling to be used for stabilizing tissue or internal structures of the urethral or pelvic floor. The other end of the card is fashioned to permit a physician to grasp and manipulate the card, or to align or connect the card with other external devices, such as those disclosed herein. The sides of the card may be adapted for use with the dilator mentioned above. Thus the card can be used to enhance both the sterility and the positional precision in a sling-placement procedure.

between the first jaw and the second jaw, and advancing the second jaw toward the first jaw to drive the guide through the pubic bone.

The invention further provides a method for passing a device through the pubic bone. The guide is driven through the pubic bone as outlined above. The guide is next retracted, leaving a path through the bone, and the device is passed through the pubic bone along the path made by the guide. The device passed by this method may be a suture, a suture passer, a quick-connect fastening device, and the like.

In an additional method of this aspect of the invention, the driver of the invention is used to advance a cannula through the pubic bone. The lumen of the cannula constitutes a channel through the pubic bone. A device may then be passed through the bone within the lumen of the cannula. Devices that may be passed by this method include a suture, a suture passer, a quick-connect fastening device, and the like.

A further method of pelvic surgery provided by the invention includes the following steps. A cannula is driven through the pubic bone with the driver of the invention. The cannula is further driven into the tissue cavity in which the first jaw of the driver is positioned. The first end of a suture is passed through the cannula and secured to a structure within the cavity. The second end of the suture is secured to the pubic bone, thereby stabilizing tissue adjacent to the cavity. According to this method, the cannula may be removed from the bone before either end of the suture is secured, or the suture within the tissue cavity may be secured before withdrawal of the cannula. The suture within the tissue cavity may be secured by stitching the suture through a tissue mass of the cavity, or by attaching the suture to a structure introduced into the cavity for stabilizing the tissue of the cavity, such as a suture button.

The invention also provides a method of pelvic surgery wherein a cannula is driven through the pubic bone and into the tissue cavity as described above, and a suture is passed through the cannula and into the cavity. The suture is passed through a structure therein to stabilize the tissue adjacent to the cavity, then the suture is passed back out along the same path through the bone, and both ends of the suture are secured to the pubic bone.

Yet another method of the invention involves driving a cannula through the pubic bone and into a tissue cavity in a first location to make a first path. The suture is then advanced into the cavity along the first path. The suture is passed through a structure of the cavity to stabilize the tissue adjacent to the cavity. The cannula is then driven through the bone and into the cavity along a second path, and the suture is withdrawn from the cavity along the second path. Both ends of the suture are then secured to the pubic bone.

The foregoing methods focus on the path of the suture: the suture may be advanced one-way into the cavity and affixed there, or the suture may be advanced and withdrawn from the cavity along the same path through the bone, or the suture may be advanced and withdrawn along two separate paths through the bone. Regardless which method is used, the tissue cavity of the method may be the vagina. Alternatively, the cavity may be a hiatal cavity made according to a method of the dilator or incision guide aspects of the present invention. Further, the tissue cavity of the method may be a transvaginally created pocket into the plane of the vaginal hiatus. Also regardless which method is used, the method may advantageously be performed on the left side of the cavity and

Another aspect of the invention provides a system for attaching a urethral sling to a suture. The system includes a urethral sling and a connector. Part of the sling is a ring member. The ring member has a central opening that cooperates with the sling to allow unidirectional passage of the connector through the opening, and to prevent retrograde passage of the connector through the opening. The connector and ring member may have a variety of configurations. One such configuration provides a ring member having several flanges and a substantially conical connector with a shoulder that contacts the flanges, preventing withdrawal of the connector from the ring member. Another configuration provides a connector having an elongate axial segment and a leading segment that is flexibly perpendicular to the axial segment. This "T" connector may cooperate with a ring member that is simply an opening in the urethral sling. The connectors of any configuration may be a attached to a suture.

This aspect of the invention provides a method for securing a sling for urethral and pelvic floor reconstruction. A sling having a suitable ring member is placed in position in a tissue cavity. A suture with a suitable connector is passed through the pubic bone, and the connector is advanced through the ring member of the sling. The suture is then fastened to the pubic bone, thus securing the sling in the cavity. The cavity may be the vagina, a cavity of the vaginal hiatus, or a cavity in the vaginal wall.

A closely related aspect of the invention provides a system for attaching a securing device to a suture. The system includes a securing device with a ring member, and a connector that attaches to a suture. The ring member and the connector cooperate as described above. The securing device may be a suture button, a staple, or a quick connect.

The method provided in this aspect of the invention is a method for securing a target tissue to the pubic bone. The securing device with a ring member is placed within or adjacent to the target tissue. A suture with a suitable connector is passed through the pubic bone, and the connector is advanced through the ring member of the securing device. The suture is fastened to the pubic bone, thus securing the target tissue to the bone.

Also part of the present invention is a bone eyelet having a sleeve and at least one crosspiece. The sleeve has an outer surface and an inner surface. The outer surface is adapted for inserting into a bone, and the crosspiece is attached to the inner surface to transect the sleeve, providing a plurality of channels in the sleeve. The crosspiece may be a plane or a rod. Alternatively, the crosspiece may be created by a piercing or crimping of the sleeve. The sleeve may have an external friction surface for contacting with the bone. It may have a flange rim for suspending the sleeve at the surface of the bone. The sleeve may also have a conical shape to facilitate advancing the sleeve into and contacting it with the bone.

The invention provides a method for securing a suture to a bone. The bone is pierced and a suture is passed through the bone. Suture ends are passed through at least two channels in the bone eyelet and the bone eyelet is placed in the opening in the bone. The suture ends are then tied, thus securing the suture to the bone. The bone may be pierced with a drill or with a driver as described above. The suture may be connected directly to a tissue or to a medical device, such as a sling, a quick connect device, a suture button, a staple, an implant, or to itself. Appropriate tension on the suture may be provided, for example with use of a suture tensioner.

Figure 8 is a cross section including a driver as in Figure 7, depicting the passage of the bone-piercing guide through the pubic bone lateral to the urethra and into the vagina.

Figure 9a is a transverse cross section taken along the line 9-9 in Figure 8, showing the distal end of the first jaw of the driver in position in the vagina, with cannulas forming a passage through the pubic bone and into the vagina.

Figure 9b is a cross section as in Figure 9a that illustrates passage through the cannulas of a suture and connecting device.

Figure 10a is a cross section as in Figure 9a, showing the pubic bone, the urethra, the hiatal region and the vagina, with sutures attached on the right and left sides of the upper vaginal wall.

Figure 10b is a cross section as in Figure 10a, showing elevation of the urethra resulting from tensioning of the sutures.

Figure 11 is a cross section view of the pelvis as in Figure 3 with the upper clamp of the driver frame assembly in place, articulating with the rigid catheter and the tongue.

Figure 12a is a cross section taken along the line 12-12 in Figure 11, and illustrates the hiatal region depicting a flat insertion tongue.

Figure 12b is a cross section taken along the line 12-12 in Figure 11, and depicts a concave insertion tongue in a hiatal cavity.

Figure 13 is a cross section view of the pelvis as in Figure 3 showing the complete driver frame assembly in place.

Figure 14 is a cross section view taken along the line 14-14 in Figure 13, showing left and right displacement of the bone-piercing guides mounted on the driver.

Figure 15 is a cross section as in Figure 3, and depicts the driver frame assembly with the bone-piercing guides penetrating to the hiatal cavity.

Figure 16 illustrates the pubic bone with the guides passing through the bone left and right of the pubic symphysis.

Figure 17 is a cross section view of the pelvis as in Figure 3 and the driver frame, with the tongue supporting an insert card and a sling in position.

Figure 18 is a cross section taken along the line 19-19 in Figure 17, and shows the position of the rigid catheter inside the urethra, the tongue, the insert card, and the sling.

Figure 19 is a cross section as in Figure 17 with the driver frame in place, and shows the driver frame with the driver removed and a cannula in position.

Figure 20 corresponds to Figure 19, but shows the driver frame with the cannula in place and a suture with quick-connect device passing through the cannula.

Figure 21 is a detail view of the area described by the curved arrows in Figure 20, and shows detail of the quick-connect device passing through the cannula toward the sling.

Figure 35 is a side elevation that depicts the passage of the T-configuration of the quick-connect device through a cannula toward the ring member of a sling.

Figure 36 is a perspective view of a bone suture fastener and a sleeve plug oriented above the pubic bone.

Figure 37a is a cross-section taken along the line 37-37 in Figure 36 and illustrates suture passing through the sleeve with the sleeve plug in place.

Figure 37b is a cross section view similar to Figure 37a showing the zipper-lock configuration of the bone suture fastener with the sleeve plug in place.

Figure 38 is a cross section view similar to Figure 37a showing the threaded configuration of the bone suture fastener with the sleeve plug in place.

Detailed Description of the Preferred Embodiments

The treatment of incontinence for intrinsic sphincter deficiency (ISD) can often be corrected surgically with the placement of a sling. This sling may consist of a wide variety of well known biocompatible materials: bovine pericardium, autograft, synthetics, cadaveric tissue, collagen/synthetic blends and the like. The sling also may be placed through a variety of surgical procedures. Slings suitable for use in urethral or bladder neck stabilization or suspension procedures and methods for implanting them are disclosed in the copending U.S. Patent Application entitled "Stabilization Sling for Use in Minimally Invasive Pelvic Surgery" (**VESITEC.023A**), filed February 13, 1998, and the identically titled U.S. Provisional Patent Application Serial No. 60/038,379, filed February 13, 1997. The extent of surgical intervention is a surgeon's preference, but all present surgical interventions require a vaginal incision. The presence of microorganisms is high in the vagina; in procedures utilizing slings of non-autologous material, a high rate of infection has been reported. The procedure described herein approaches sling placement in a different manner from that requiring a vaginal incision. The vaginal hiatus is approached just under the distal urethra and a cavity is dilated within the tissue parallel to the urethra and upper vaginal wall. This device and resultant pocket provide access for placement of the sling in the treatment of ISD and urethral hypermobility. The dilator also may be used in an approach from within the vagina to create a pocket in the desired location approaching the bladder neck.

Turning now to the drawings, Figure 1 shows the urethra and the vagina 4 with the vaginal wall 8 in between. The dotted line in Figure 1 represents an incision site in the vaginal hiatus 2. The vaginal hiatus 2 is the external tissue between the urethra and the vagina 4, as well as the tissue deep to that external tissue. The vaginal wall 8 is intended to refer to all interior surfaces of the vagina 4.

The series of figures from 2a to 2g demonstrates a sequence having to do with one aspect of the present invention, referred to herein as the dilator 10. The dilator 10 consists of two distinct functional units, the insertion spreader 12 and the handle 18. The insertion spreader 12 can have the appearance of a split tube, and each half of the insertion spreader 12, or each half of the split tube, can be an elongated semi-cylindrical spreader guide 14. The invention contemplates spreader guides 14 shaped other than semi-cylindrically, such as spreader guides 14

may be calibrated or otherwise marked to indicate the depth of its insertion, to allow a physician to accurately determine the proximity of the tip of the needle 24 to an internal structure, such as the bladder neck 47. In addition to a determination of the depth of penetration, the needle 24 may also provide a path for simplified insertion of the spreader 12 of the invention.

Using an embodiment of the dilator 10 wherein the distal ends 15 of the guides 14 are adapted for cooperating with a needle 24, the spreader 12 is moved to the open position, and the spreader 12 spreader guides 14 are placed near the needle 24, then the spreader 12 is moved to the closed position. In the closed position the spreader guides 14, at least at their distal ends 15, substantially conform to the shape of the needle 24 and may follow its path into the tissue 9, as in Figure 2b. The spreader guide 14 is then inserted to the desired depth, at which point the needle 24 may be withdrawn, as in Figure 2c. Then, as before, the handles 18 are moved closer together, thus moving the spreader guides 14 away from each other to the open position (Figure 2d). The ratcheting lock 22 portion of the handles 18 holds the handles 18 together and the spreader guides 14 apart. Movement of the spreader guides 14 to the open position creates the cavity desired for insertion of a medical device, or for performing a desired surgical procedure.

As an alternative embodiment of this method, an additional step may be preformed to facilitate creation of the cavity. In this embodiment, the target tissue 9 is fluid-dissected by injecting a solution into the tissue 9 prior to advancing the insertion spreader 12 into the tissue 9. This additional step of hydro-dissection may be preformed using a variety of physiologically suitable buffers or solutions. This additional step provides an advantage in some cases, because hydro-dissection may be tissue-selective with respect to the vaginal hiatus 2 and the urethra. That is, hydro-dissection may tend to preferentially dissect hiatal tissue without impinging upon urethral or bladder tissue. Accordingly, a first step of hydro-dissection that creates a saline bolus, may predissect the tissue without affecting the integrity of the urethra. The subsequent step of passing the insertion spreader 12 into the tissue is therefore simplified, and the movement of the spreader guides 14 into the open position is also simplified, because a substantial portion of the cavity is already created by the process of hydro-dissection.

In one method of hydro-dissection and subsequent cavity opening with use of the dilator 10, a needle is inserted into the upper vaginal wall 8 and the saline solution is delivered into the deep tissue of the vaginal hiatus 2. The deep tissue of the vaginal hiatus 2 is thereby dissected by the injected solution. Subsequent insertion of the spreader 12 through the external skin of the vaginal hiatus 2 provides a route of entry that is less susceptible of infection than may be the case where a tissue cavity is created entirely transvaginally. Because the interior of the vagina 4 harbors more microorganisms than the surface of the vaginal hiatus 2, and is also much more difficult to surface sterilize, the exterior vaginal hiatus 2 may often be the preferred route of entry for creating a tissue cavity for urethral and pelvic floor reconstruction. However, certain circumstances may dictate creation of a tissue cavity transvaginally; the dilator 10 of the invention and the methods of its use are fully adaptable to creation of a cavity transvaginally. Thus, the present invention provides a surgeon with a convenient means of opening a tissue cavity and with alternative avenues of entry to the tissue cavity. Additional devices and methods for transvaginal urethral or pelvic floor reconstruction and urethral or bladder neck stabilization or suspension, suitable for use in

supported on a card 30 with the assistance of the dilator 10 of the invention, will be evident to those of skill in the art.

Figures 2e, 2f and 2g show the steps of the method after the cavity is created. In Figure 2e the card 30 holding the sling 42 is aligned with the spreader guides 14 of the dilator 10. In Figure 2f the card 30 is inserted into the cavity by sliding the sides of the card 30 along the semicircular tracks provided by the spreader guides 14 of the dilator 10. Figure 2g shows the card 30 in position in the tissue cavity after removal of the dilator 10. As can been seen in Figure 2g the proximal portion 38 of the card 30 and the articulation opening 40 remain outside the cavity for continuing or subsequent interaction with accessory tools, such as those which are disclosed below in a discussion of other aspects of this invention.

The placement of the sling 42 or some other medical device by the method of this aspect of the invention preferably precedes the securing of such a medical device inside the tissue cavity. The invention contemplates securing the sling 42 or other medical device in several different ways. In one embodiment the sling 42 may be placed in the cavity to be sutured therein by a suture 88 entering the cavity from the upper vaginal wall 8. In another embodiment the sling 42 may be stapled or anchored into place subsequent to its positioning with the use of the card 30. Suturing of the sling 42 into position also may be accomplished percutaneously, or with the suture being advanced from above or through the bone. Additional devices and methods for percutaneous and hiatal approaches for urethral or pelvic floor reconstruction and urethral or bladder neck stabilization or stabilization, suitable for use in connection with the present invention, are disclosed in the copending U.S. Patent Application entitled "Percutaneous and Hiatal Devices and Methods for use in Minimally Invasive Pelvic Surgery" (**VESITEC.029A**), filed February 13, 1998, and the identically titled U.S. Provisional Patent Application Serial No. 60/038,171, filed February 13, 1997.

Preferred methods of securing the sling 42 in place may involve anchoring the sling 42 to a bone via a suture 88 and a bone anchor, or may involve attaching the sling 42 to a suture 88 which passes through a bone, such as the pubic bone. This preferred embodiment of the method of attaching the sling 42 into place after it has been delivered into a tissue cavity by the card 30 of the invention will be discussed below in connection with other aspects of the present invention. It will be evident to those of ordinary skill in that art that the method of this aspect of the invention will be applicable to the positioning of several kinds of medical devices. Such medical devices may be secured into place after their positioning by one of several known techniques.

Another aspect of the invention provides an incision guide 50 (see Figure 5) for cutting a cavity between the urethra and the vagina 4, in the hiatal tissue. The incision guide 50 consists of a rigid catheter 52 and a cutter 54, and may also consist of several other accessories to enhance or vary the performance of the incision guide 50. The rigid catheter 52 is a modified Foley-type catheter, preferably having a shaft of metal or other rigid material over the surface of the catheter.

The catheter 52 is inserted into the urethra and an integral bladder neck balloon 53 is inflated. (Figure 3.) The rigid catheter 52 straightens the urethra and extends externally to provide a guide for attachment of devices which advance parallel to the urethra along the central hiatus plane. The balloon 53 holds the catheter 52 in place.

as the bipolar cutting loop, consists of a pair of wires, one flexible and one rigid, through which a current is passed to heat the loop.

Preferred dimensions of the cavity that is created may be from 1 to 3.5 cm deep and may have a width ranging from the width of a needle 62 to approximately 3.5 cm. The most preferred width for applications in which a sling 42 is to be installed is approximately 2 to 4 cm. The preferred depth of penetration of the cutter 54 is, of course, a function of the particular anatomy of a given patient, and is to be determined by the surgeon after insertion of the rigid catheter 52 and reference to the indicia 58 thereon.

Modified embodiments of the incision guide 50 include the attachment of various other devices to further optimize the control that a surgeon may exercise over the depth and direction of penetration of the cutter 54 device. One such modification is to add one or more stops 60 to the device, as shown in Figure 5. In one embodiment of this modification, one stop 60 is movably and lockably positioned on the catheter 52. This stop 60 may have the form of a ring or a block, and may be locked at a particular position of the catheter 52 by means of a thumb screw or a spring snap that articulates with the indicia 58 on the catheter 52 at various positions along its length. The stop 60 slides onto the end of the end of the catheter 52 and may be locked in a certain position on the catheter 52 to prevent advancement of the cutter 54 past the position of the stop 60. The cutter 54 may also have a block 61 intended to abut the stop 60 that is placed on the catheter 52. Therefore the cutter 54 which slides along the catheter 52 may attach by means of a stop block 61, or by other means of attachment that may similarly function as a stop block 61.

This aspect of the invention provides a method for creating a cavity in the vaginal hiatus 2. The method begins with insertion into the urethra of the rigid catheter 52. (Figure 3.) The preferred catheter 52 is, as discussed above, provided with indicia 58 to indicate the position of the bladder neck 47. The catheter 52 extends from the distal urethra of the patient, providing a linear guide for the cutter 54. According to the method, the position of the bladder neck 47 is determined. Next the cutter 54 is positioned on the catheter 52 and is advanced toward the patient along the catheter 52 until the cutter 54 contacts and penetrates the vaginal hiatus 2. (Figure 5.) The cutter 54 is then inserted into the vaginal hiatus 2 to a predetermined depth, thus creating a cavity in the vaginal hiatus 2 that does not extend to the bladder neck 47.

This method allows a surgeon to make an incision into the vaginal hiatus 2 in a way that optimizes the safety, reproducibility, and reliability of the procedure. With a preferred embodiment of the incision guide 50 as discussed above, the depth of insertion may be very precisely controlled, preventing damage to the bladder neck 47. Likewise, the displacement between the urethra and cutter 54 is maintained constant, thus assuring that creating the cavity will not compromise the urethra or the vaginal wall 8.

The various embodiments of the incision guide 50 also provide precise control of the width of the incision. For example the incision width may be that of a needle 62 (Figure 6a) of a selected gauge, or it may be the width of a selected blade 64 (Figure 6b), or it may be the width determined by the dimensions and orientation of the wires in a bipolar knife. An additional benefit of the method of the invention is that, because the cutter 54 tracks along the rigid catheter 52, and therefore tracks along the urethra itself, there is a constant lateral relationship between

The driver 70 of the invention may be described as having four basic parts: a first jaw 72, a slide bar 80, a second jaw 82, and a bone-piercing guide 84. (Figure 7.) The first jaw 72 has a distal end 74 and a proximal end 78. The distal end 74 is adapted for inserting into a tissue cavity and the proximal end 78 of the first jaw 72 is attached to the slide bar 80. The slide bar 80 connects the first or fixed jaw 72 with the second or moveable jaw 82. The second jaw 82 slides along the slide bar 80, with a releasable ratcheting action, toward the first jaw 72. The bone-piercing guide 84 attaches to the second jaw 82, and advances toward the first jaw 72 as the second jaw 82 is ratcheted along the slide bar 80.

A stop 86 on the slide bar 80 prevents further closing of the jaws once the sharp end 96 of the cannula 90 exits the bone and is even with the first jaw 72. The first jaw 72 has a slot 76 so that the sharp end 96 of the cannula 90 does not actually contact it when exiting the bone. (Figure 8.) The driver 70 may be equipped with a double cannula jaw 82 (not shown) so that parallel passages may be created through the bone simultaneously.

It is the function of the first or fixed jaw 72 inside a tissue cavity to provide a counterpressure on the bone opposite the pressure applied by the bone-piercing guide 84. Accordingly, the distal end 74 of the first jaw 72 may have a shape adapted to provide positions that can appress the inferior region of the pubic bone 45 lateral to the pubic symphysis without crushing the urethra 6. Such a configuration of the distal end 74 of the first jaw 72 is shown in cross section in Figures 24a and b, 26a and b, and 27a; a detail view of a portion of the edge of the distal end 74 of the first jaw 72 is shown in Figure 25. In these figures, the distal end 74 comprises a tongue 114 with a central depression 136 and elevated edges 138. The edges 138 may have contact pins 140 adapted for piercing the tissue lying between the pubic bone 45 and the elevated edge 138 of the tongue 114. At the elevated edge 138 there also may be a gap 144 through which a guide 84 may pass without contacting the tongue 114.

Any device with opposing jaws having one jaw adapted for insertion into a tissue cavity may preferably have a tongue configuration as described above. The choice of a desirable configuration of the distal end 74 of the first jaw 72 may be determined by one of ordinary skill in the art, taking into account anatomical considerations, the particular procedure involved, and the like.

The pubic bone is an especially important structure for piercing in surgical applications. This is true for at least two reasons: the first is that there are soft tissue structures in the proximity of the pubic bone whose dimension or displacement can result in several medical problems. The second reason is that the pubic bone is a relatively low density bone and therefore may be pierced without the application of undue force, if the force is properly oriented. The fact that the pubic bone may be pierced creates the possibility of stabilizing a soft tissue structure near the pubic bone by attaching a device or a suture to the soft tissue structure and stabilizing it by attachment to the relatively immovable pubic bone. In addition, by piercing through the bone, the suture locking and tissue securing method may be accomplished from the superior/anterior bone surface, which is much more accessible than the posterior/inferior surface. The prior need to work near or at the posterior/inferior surface of the pubic bone arose from the proximity of this surface to the structures most often sought to be stabilized. With the methods and devices of the present invention, however, passage of suture through the pubic bone combines the desired proximity to structures beneath the bone, with the convenience and simplicity of introducing and securing suture through the

introducing into a cavity a medical device, also may be used in connection with the driver 70 of the invention. In this particular combination the first jaw 72 of the driver 70 may be configured to support the card 30 or connect with the articulation opening 40 of the card 30 such that introduction of the first jaw 72 into the tissue cavity places the device in the appropriate position within the cavity. Subsequent operation of the driver 70 directly positions the bone-piercing guide 84 in the proper orientation with respect to the device supported on the card 30. Therefore, use of the driver 70 in combination with devices of other aspects of the present invention may result in several beneficial methods for surgery on the urethral floor and other structures of the pelvis.

This method creates a path through the pubic bone, which path is useful for passing sutures 88 or medical devices through the pubic bone. There are several alternative embodiments of this method. In one embodiment the guide 84 is passed through the bone to create a path through the bone and then the guide 84 is removed, leaving the path in the bone and in the tissue. After removal of the guide 84, medical devices such as a suture 88, a suture passer, or a suture securing device 126 may be passed along the path through the bone that was created by the bone-piercing guide 84. Any device capable of passing a suture through tissue may be used in accordance with the present invention, including the suture passers and methods of their use, disclosed in U.S. Patent No. 5,611,515, issued March 18, 1997 to Benderev et al.

The driver 70 of the invention also may be used in a different orientation such that the movable jaw is adapted for insertion into a tissue cavity and for driving a device into the pubic bone from the posterior-inferior surface. As an example of a preferred embodiment, a sling 42 with pre-attached push-in bone anchors (not shown) is positioned on an insert card 30 and is placed into a tissue cavity with the assistance of the dilator 10 or the incision guide 50 of the invention, or by using both in combination. Next, the push-in anchors are oriented to face and contact the pubic bone. Finally, the movable jaw of the driver 70 is placed below the push-in anchors of the sling 42 and the fixed jaw of the driver 70 is placed against the patient's abdominal surface such that the pubic bone lies between the fixed jaw and the movable jaw. The movable jaw is then advanced toward the fixed jaw such that the push-in bone anchors are driven into the posterior-inferior surface of the pubic bone and the sling 42 is secured in place.

Other means of securing a sling 42 in place by using push-in type bone anchors are also contemplated in the invention. For example, a pivoting or otherwise manipulable tongue or insert card 30 that supports and positions the sling 42 may be forcefully angled against the pubic bone sufficient to drive into the pubic bone the push-in type anchors from the posterior-inferior surface of the bone. In another embodiment, cannulas 90 are driven through the bone, both left and right of the midline, such that a path into the pubic bone is provided for initial guidance of push-in anchors. As the cannulas 90 on either side of the midline are withdrawn from the pubic bone, the push-in anchors (not shown) are pressed upward against the bone and initially follow the path of the cannulas 90. Thus, a guide hole is created by the cannulas 90 for the anchors. The application of additional upward pressure seats the anchors and the sling 42 is secured in place.

A preferred embodiment of the invention uses a cannula 90 as the bone-piercing guide 84. (Figure 9a.) The lumen of the cannula 90 constitutes a path through the tissue and through the pubic bone. Accordingly, the

Without the use of an additional device, attaching the suture 88 to tissue within the cavity may make possible amelioration of certain incontinence conditions that arise from hypermobility of the urethra or from intrinsic sphincter deficiency. This is done simply by attaching the suture 88 to tissue and then providing an appropriate tension. This tends to elevate the tissue, which therefore elevates the urethra at that position a distance A (compare Figure 10a to 10b), eliminating or easing the condition causing urinary incontinence.

An alternative embodiment of this aspect of the invention uses the driver 70 to insert a cannula 90 into the tissue cavity by passing it through the pubic bone as described above. In this embodiment, however, the end of the suture 88 which is advanced through the cannula 90 and into the tissue cavity is passed through a structure 93 within the tissue cavity. It is subsequently passed back out of the cavity and secured to the pubic bone, along with the second end of the suture 88. In this embodiment of the invention, the structure 93 through which the suture 88 may be passed include a suture button 94 or grid, a sling 42, and a tissue mass adjacent the cavity (creating stitches 92). The cannula 90 advantageously has a sharpened end 96 and a reinforced stiffness, to facilitate its passage in a straight line through the bone and to minimize skimming along the surface of the bone. Further, for embodiments of this method, the cavity is preferably a cavity in the vaginal hiatus 2 created according to one of the other methods of this invention. The cavity also may be the vagina 4, or a cavity in the hiatal tissue created transvaginally.

This method is advantageous particularly for the stitching of a tissue mass for stabilization of the urethra floor or other pelvic structures. (Figure 10.) Because the suture 88 enters and then again exits the tissue cavity, it may be passed through several stitching 92 points in the tissue before it is withdrawn through the cannula 90 and out to the pubic bone. Both ends of the suture 88 may be secured to the pubic bone in a variety of ways, many of which will be explained in detail below.

This method may be advantageously practiced with the additional assistance of a suture passer device. The suture passer is advanced through the cannula 90 and into the tissue cavity upon completion of the desired number of sutured stitches 92 within the cavity, the suture 88 is grasped by the suture passer, and withdrawn through the cannula 90 to properly position it at the surface of the pubic bone for attachment. This method may be preferably used for tensioning, stabilization, or elevation of a tissue mass adjacent to the urethra or adjacent to another soft tissue structure in the pelvis that may be in need of stabilization or reorientation. The fact that the suture 88 is secured to the bone creates a stability for the target tissue mass that is desirable in many cases. It also may be desirable to use this method in securing in a tissue cavity a pharmacological implant, a prosthetic device, or a therapeutic device.

This aspect of the invention provides an additional method for pelvic surgery wherein the driver 70 is used to pass a guide 84 through the pubic bone along a first path, proceeding into the tissue cavity at a first position. A suture 88 is then passed through the cannula 90 into the cavity. The driver 70 is then used to create a second path through the pubic bone, arriving at a second location within the tissue cavity. The suture 88 which was passed along the first path through the pubic bone and into the cavity may then be passed along the second path out of the cavity and through the pubic bone at the second position. Both ends of the suture 88 may then be secured to

of an insert card 30 as discussed above, or by other surgical procedures known in the art. With the cannula 90 in the cavity adjacent the sling 42, the suture 88 is attached to the sling 42 and to the pubic bone.

This method is embodied in a technique wherein the cannula 90 is withdrawn before the suture 88 is secured on either end. The method also contemplates withdrawal of the cannula 90 after the sling 42 is secured but before the suture 88 is secured to the bone. In addition to attaching the sling 42 with sutures 88, this method contemplates an indirect attachment of the sling 42 to sutures 88 by directly attaching the sling 42 to devices which are themselves attached to sutures 88. An example of such an indirect attachment to a suture 88 is a securing device 126 as disclosed herein. This method may advantageously involve use of the devices of other aspects of the present invention. The tissue cavity may be made either by the dilator 10 or the incision guide 50, or by using both together, and the sling 42 may be delivered to its proper position in the cavity with aid of the insert card 30 as discussed above. Depending on the particular manner in which the insert card 30 articulates with a driver 70, the cooperative use of the insert card 30 may precisely position the sling 42. This will cause the bone-piercing guide 84 to meet the sling 42 at the appropriate straight line position as is desirable in this method.

Another aspect of this invention provides a driver frame assembly 100. The driver frame assembly 100 serves to align, support and stabilize both the patient's pelvis and the devices of the invention in procedures for reconstructing the urethral and pelvic floor or for performing other methods of pelvic surgery. The driver frame assembly 100 has an upper clamp 102, a rigid catheter 52, a cavity tongue 114, a lower clamp 120, and at least one driver 70. The upper clamp 102 of the driver frame assembly 100 has a head portion 104, a descending arm 106 and a base portion 108. The head portion 104 has a compression foot 110 that is used to compress a patient's abdominal surface against the pubic bone. The compression foot 110 has stabilizing pins 112 that extend downward therefrom and that pierce the patient's skin 48, penetrating the abdomen at a position adjacent to the superior surface of the pubic bone. The compression foot 110 may be pressed against the abdomen of the patient with, for example, a threaded screwing mechanism, a ratcheting or piston mechanism, or a linkage mechanism. The stabilizing pins 112 are designed to be of a length that makes it impossible for the pins 112 to cause damage to any abdominal or pelvic organs. At the same time the stabilizing pins 112 have dimensions making them sufficiently strong to resist the lateral forces exerted with operation of the driver 70.

The rigid catheter 52 portion of the driver frame assembly 100 functions much as the rigid catheter 52 of the incision guide 50, as discussed above. The catheter 52 is intended to straighten and elongate the urethra, as well as to assist in identifying the position of the urethra, the bladder 46, and bladder neck 47. The rigid catheter 52 is of sufficient length to extend outward beyond the distal urethra of the patient. This external extension of the rigid catheter 52 provides a structure with which the frame assembly may articulate and attach. (Figure 11.)

The tongue 114 portion of the driver frame assembly 100 is adapted for insertion into a tissue cavity, such as the vagina 4 or a hiatal cavity prepared prior to insertion of the tongue 114. In a preferred embodiment, the tongue 114 has a central depression 136 and elevated edges 138 (Figure 12b), allowing compression of the tongue 114 sides against the inferior surface of the pubic bone to counter the pressure of the compression foot 110.

urethra is elongated and straightened. (Figure 11.) The catheter 52 also aids in determining the position of the bladder 46 and the bladder neck 47. The tongue 114 of the driver frame assembly 100 is placed into the tissue cavity, and also may be attached to the rigid catheter 52. (See Figures 11 and 12.) Preferably an insert card 30 holding a medical device, for example, a urethral sling 42, is inserted into the cavity using the tongue 114 as a guide. (Figure 18.) The upper clamp 102 is attached to the tongue 114 and to the catheter 52, and the compression foot 110 is compressed against the patient's abdomen, after palpation to determine the proper position of the stabilizing pins 112 relative to the superior surface of the pubic bone. The compression foot 110 is tightened against the patient's abdomen to prevent slipping of the bone-piercing guide 84, and to further immobilize the soft tissues of the pelvis. (Figure 11). Further stabilization is achieved with attachment of the lower clamp 120 which is done by sliding the buttock plate 122 beneath the patient and firmly attaching the ascending arm 124 of the lower clamp 120 to the base portion 108 of the upper clamp 102. (Figure 13.)

With the driver frame assembly 100 properly installed along the patient's midline, the driver 70 portion of the driver frame assembly 100 may be mounted on the descending arm 106 of the upper clamp 102. (Figure 13.) Care is taken to assure that the bone-piercing guides 84 of the driver 70 are positioned such that they will enter the pubic bone. Then the second removable jaw of the driver 70 is advanced downward along the slide bar 80 and the guides 84 are advanced into the abdominal surface and through the pubic bone, emerging within the tissue cavity near the medical device supported on the card 30. (Figure 15.)

In a preferred example, the bone-piercing guides 84 are cannulas 90 and the medical device supported on the card 30 is a sling 42. (Figures 17 and 18.) In such an embodiment, the proximity of the cannulas 90 with the sling 42 permits suturing or other attachment through the lumen on the cannula 90 to the desired location on the urethral sling 42. (Figure 19.) After attachment of suture 88 directly or indirectly (see Figures 21-23) to the sling 42, the cannulas 90 are removed, leaving behind the suture 88, which is then secured to the pubic bone. (Figure 28.)

In another embodiment of this aspect of the invention, a concave insertion tongue 114 is used to provide counterpressure for driving cannulas 90 through the pubic bone 45. The concave tongue 114 is inserted into a cavity, such as, for example, a hiatal cavity or the vagina 4, and the compression foot 110 of the driver frame assembly 100 is placed against the patent's pubic bone 45. (Figure 24a.) The concave tongue has a central depression 136 and elevated edges 138, allowing the edges 138 of the tongue 114 to provide counterpressure to the posterior/inferior surface of the pubic bone 45, while the compression foot 110 and the cannulas 90 apply pressure to the opposite (anterior/superior) surface of the bone 45. (Figure 24b.)

The central depression 136 of the tongue 114 prevents the urethra 6 from being crushed upon application of counter pressure on the bone 45 by elevated edge 138 of the tongue 114. (Figure 24b.) The edge of the tongue may also have a gap 144 to allow the cannula 90 to pass through the plane of the elevated edge 138 without the cannula 90 impacting against the tongue 114. The edge 138 may also have contact pins 140 of a configuration and position to pierce through soft tissue and fascia to contact the surface of the pubic bone 45 and prevent slippage of the tongue 114. (Figure 25.)

of the conical tip 131, such that there is a substantially flat shoulder 129 behind the tip 131. Accordingly, the arrowhead connector 132 is adapted for cooperating with the reinforced ring member 44 having flanges 142 that protrude into the central opening 128. As the tip 131 penetrates the central opening 128, the flanges 142 move aside, allowing passage of the tip 131. However, once the entire conical portion of the tip 131 has passed through the central opening 128, the flanges 142 return to their initial orientation around the central opening 128 and rest against the shoulder 129, resisting retrograde movement of the connector 130 through the ring member 44. (Figures 22, 23, 30, 32.) Since the cylindrical portion 133 behind the shoulder 129 of the arrowhead connector 132 has a means for connecting to a suture 88, the passage of the connector 130 through the ring member 44 creates a connection between the suture 88 and the sling 42. (Figure 32a.) By this method of connecting suture 88 to sling 42, there is no need for stitching or tying knots to the sling 42, which greatly simplifies and accelerates the securing procedure.

Another preferred embodiment of the securing device 126 has a connector 130 with two perpendicular cylindrical members 135, 137 wherein the members 135, 137 are substantially flexibly attached one to the other at a flexible joint 139. (Figure 34.) The rear cylinder 135 has a means of attaching to a suture 88, while the leading cylinder 137 is adapted for passage through the ring member 44. As this embodiment of the connector 130, referred to herein as the T connector 134, is inserted into a cannula 90 for advancement toward the sling 42, the perpendicularity between the two cylindrical members 135, 137 is distorted, and the leading cylinder 137 assumes a position that is more closely parallel, rather than perpendicular, to the rearward cylinder 135. (Figure 35.) However, after the T connector 134 has passed through the cannula 90 and the leading cylinder 137 of the T connector 134 has also passed through the ring member 44 of the sling 42, the angular relationship between the two cylindrical members 135, 137 reverts to perpendicular. (Figure 33.) In this conformation, the connector 130 may not pass back through the ring member 44, and a secure connection between the suture 88 and the sling 42 is therefore established.

This aspect of the invention provides a method for simple, minimally invasive placement and securing of a sling 42 in a tissue cavity. A tissue cavity, such as a cavity in the hiatal tissue, is created by use of, for example, the dilator 10 or the incision guide 50 of the invention. Alternatively an existing tissue cavity, such as the vagina 4, may be selected for placement of the sling 42. In addition, a tissue cavity in the hiatal tissue may be created by inserting a dilator 10 or an incision guide 50 through the upper vaginal wall 8. A sling 42 is then placed into the cavity in its desired location. This step is preferably performed with the use of the insert card 30 of the invention, wherein the insert card 30 carries and supports the sling 42 in its appropriate position within the cavity until it secured there. (Figure 18.)

A cannula 90 is driven through the pubic bone using, for example, either the driver 70 of the invention or the driver frame assembly 100 of the invention. (Figure 18.) The cannula 90 is then further driven through tissue until it approaches and aligns with the sling 42, (Figure 19.) which is equipped with ring members 44. A connector 130 attached to the suture 88 is then inserted into the lumen of the cannula 90 and advanced therethrough until it contacts with and passes through the ring member 44 of the sling 42. (Figures 20, 21, 22.) At this point, the

employed in connection with a securing device 126 discussed above to greatly accelerate and simplify the steps in securing a tissue mass or a urethral sling 42 in a tissue cavity. (Figures 32, 33.) Accordingly, the bone eyelet 150 may be used in connection with the driver 70 aspect of the this invention, as well as the driver frame assembly 100 aspect of the invention. It may further be adapted for use with other means of advancing a suture 88 through a pubic bone.

A further aspect of the present invention provides a bone suture fastener 170 for quick and simplified connection of a suture 88 to a bone. (Figures 36-38.) The suture fastener 170 consists of a sleeve 172 having an opening 174 at each end, and a sleeve plug 178. The sleeve 172 is provided with a friction surface 180 for contacting the sleeve plug 178 and for preventing disengagement of the plug 178 from the sleeve 172. Different embodiments of the bone suture fastener 170 have a sleeve 172 that is substantially conical or cylindrical and a sleeve plug 178 that is likewise substantially conical or cylindrical. In one embodiment the friction surface 180 is a plurality of friction flanges 184 partially occluding one opening 174 of the suture fastener sleeve 172. (Figures 36, 37a.) These flanges 184 flex is one direction to allow insertion of the sleeve plug 178 into the sleeve 172 and then prevent release of the sleeve plug 178 from the sleeve 172. In another embodiment, the friction surface 180 is threaded 182 and the sleeve 172 is substantially cylindrical. (Figure 38.) The sleeve plug 178 is likewise threaded 182 and is adapted for frictionally contacting the threads 182 of the suture fastener sleeve 172. An additional embodiment, the sleeve plug 178 may have a series of distortable angled rings 179 along its length, wherein the circumference of the top of each ring 179 is smaller than the circumference of the bottom of the same ring 179. The suture 88 may be tied directly to the sleeve plug 178. In this embodiment, the friction surface 180 of the sleeve 172 has a rim 183 adapted to allow unidirectional passage of the sleeve plug 178 and to prevent retrograde passage thereof, resulting in a one-way zipper-lock action. This embodiment allows a surgeon to adjust the tension on the suture 88 simply by pulling the sleeve plug 178 through the sleeve 172 to the desired position. (Figure 37b.) In any of these embodiments, a flange rim 186 may extend around the circumference of one end of the sleeve 172 to prevent sinking of the bone suture fastener 170 past the surface of the bone. (Figure 38.)

This aspect of the invention provides a method for quick and simple securing of a suture 88 that has passed through a bone. According to the method, one or multiple ends of a suture 88 may be passed through the sleeve 172 of the suture fastener 170 and the suture fastener 170 may be advanced along the suture 88 until it contacts the bone through which the suture 88 passes. (Figure 36.) The sleeve 172 is secured in the bone near the bone surface either by a friction surface 180 on the outside of the sleeve 172, or by a flange rim 186 extending around the circumference of one end of the sleeve 172. With the sleeve 172 in place, and the suture 88 passing therethrough, the suture 88 may be tensioned to approximately the desired tension and the sleeve plug 178 partially inserted into the opening 174 of the sleeve 172 at the surface of the bone. Any desired tensioning or release of tension in the suture 88 is done prior to final seating of the sleeve plug 178 in the sleeve 172 against the friction surface 180. (Figures 37a and 38.) When the sleeve plug 178 is appropriately seated against the friction surface 180, the suture 88 is secured in place at the surface of the bone, and excess suture 88 is cut off by the surgeon.

WHAT IS CLAIMED IS:

1. A dilator for creating a cavity, comprising:

an insertion spreader comprising a first and a second elongated guide, said first and second guides each having a distal end and a proximal end, said first guide being parallel to said second guide, said guides of said insertion spreader being movable between a closed position and an open position;

a first and a second handle, each of said handles having a first end and a second end, wherein said first end of said first handle is attached to said first guide, said first end of said second handle is attached to said second guide, and said second end of each of said handles is adapted to allow a person to grasp and manipulate said dilator; and

a pivot intermediate said first end and said second end of each of said handles, said handles being movably connected at said pivot, whereby movement of said handles about said pivot causes a displacement of said guides to move said guides between said closed and said open positions.

2. The dilator of claim 1 further comprising a ratcheting lock for maintaining said insertion spreader in a fixed position.

3. The dilator of claim 1 wherein said distal ends of said guides are sharpened for penetrating a tissue.

4. A method of creating a cavity in a tissue comprising the steps of:

providing a pair of parallel guides that are moveable from a closed position in which they are relatively close together to an open position in which they are farther apart;

advancing said guides into said tissue, wherein said guides are in said closed position; and

moving said guides into said open position to create a tissue cavity therebetween.

5. The method of claim 4 further comprising the step of advancing a needle into said tissue along an insertion path, prior to the step of advancing said parallel guides into said tissue, said needle having a protruding end exterior said tissue, wherein said guides are positioned about said protruding end of said needle so that said guides can be moved into said tissue along said path of said needle.

6. The method of claim 4 wherein said tissue is a vaginal hiatus.

7. The method of claim 6 further comprising the step of performing an episiotomy of said vaginal hiatus.

8. The method of claim 4 wherein said tissue is a vaginal wall.

9. The method of claim 4 wherein said tissue is fluid-dissected by injection of a solution into said tissue prior to advancing said parallel guides into said tissue.

10. A system for advancing a medical device into a tissue cavity, said system comprising:

a card having a distal portion and a proximal portion, wherein said distal portion is adapted to support said medical device, and said proximal portion is adapted for manipulation of said card;

a medical device carried by said card;

stopping the sliding step with the cutter located proximal to said bladder neck to avoid injuring the bladder.

21. A method of advancing a sling into a tissue cavity comprising the steps of:

inserting a catheter into a urethra, said catheter being adapted for indicating the position of a bladder neck;

determining the position of said bladder neck with said catheter;

sliding a cutter along said catheter into a vaginal hiatus, thereby creating a cavity in said vaginal hiatus;

stopping the sliding step with the cutter located proximal to said bladder neck to avoid injuring the bladder; and

advancing a card into said cavity, said card having a sling positioned on a distal end thereof, whereby said sling is advanced into said cavity.

22. A driver for driving a guide through a pubic bone, said driver comprising:

a first jaw having a distal end and a proximal end, wherein said distal end of said first jaw is adapted for insertion into a tissue cavity

a slide bar attached to the proximal end of said first jaw;

a second jaw for opposing said first jaw, said second jaw being slidably connected to said slide bar, said second jaw being capable of advancing toward said first jaw along said slide bar; and

a guide being attached to said second jaw, wherein said guide is moved toward said first jaw by advancing said second jaw along said slide bar, and wherein said guide is adapted for passing through said pubic bone.

23. The driver of claim 22 wherein said guide is a cannula.

24. The driver of claim 22 wherein said guide is a needle.

25. A method of driving a guide through a pubic bone comprising the steps of:

providing a driver for driving a guide through a pubic bone, said driver comprising a first jaw, a slide bar, a second jaw and a guide, said second jaw being slidably connected to said slide bar, said guide being attached to said second jaw, wherein said guide is moved toward said first jaw by advancing said second jaw along said slide bar, and wherein said guide is adapted for passing through said pubic bone;

inserting said first jaw into a cavity below said pubic bone;

positioning said driver to align said pubic bone between said first jaw and said second jaw; and

advancing said second jaw toward said first jaw to drive said guide through said pubic bone, thereby creating a path through said pubic bone.

26. The method of claim 25, further comprising the steps of:

removing said guide from said path; and

passing a device through said pubic bone along said path.

advancing said second jaw toward said first jaw to drive said cannula through said pubic bone;

advancing said cannula into said cavity;

providing a suture having a first end and a second end;

passing said first end of said suture through said cannula and into said cavity;

attaching said suture to a tissue in said cavity by passing said first end of said suture through said tissue;

retracting said first end of said suture through said cannula; and

securing said suture to said pubic bone.

40. A method of pelvic surgery comprising the steps of:

providing a driver for driving a cannula through a pubic bone, said driver comprising a first jaw, a slide bar, a second jaw and said cannula, said second jaw being slidably connected to said slide bar, said cannula being attached to said second jaw, wherein said cannula is moved toward said first jaw by advancing said second jaw along said slide bar, and wherein said cannula is adapted for passing through said pubic bone;

inserting said first jaw into a cavity;

locating said pubic bone;

positioning said driver in a first position to align said pubic bone between said first jaw and said second jaw;

advancing said second jaw toward said first jaw to drive said cannula through said pubic bone along a first path;

advancing said cannula into said cavity;

providing a suture having a first end and a second end;

passing said first end of said suture through said cannula along said first path through said pubic bone and into said cavity;

attaching said suture to a tissue in said cavity by passing said first end of said suture through said tissue;

positioning said driver in a second position to align said pubic bone between said first jaw and said second jaw;

advancing said second jaw toward said first jaw to drive said cannula through said pubic bone along a second path;

advancing said cannula into said cavity;

retracting said first end of said suture through said cannula along said second path through said pubic bone; and

securing said first end and said second end of said suture to said pubic bone.

41. A method of stabilizing a urethral sling relative to a pubic bone comprising the steps of:

creating a cavity in a vaginal hiatus;

a sleeve and a sleeve plug, wherein said sleeve comprises at least two openings adapted to allow passage of a suture through said openings, said sleeve being further adapted for inserting into a bone and having a surface for frictionally contacting with said sleeve plug, wherein said sleeve plug is adapted for occluding at least one of said openings.

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Fig. 2B

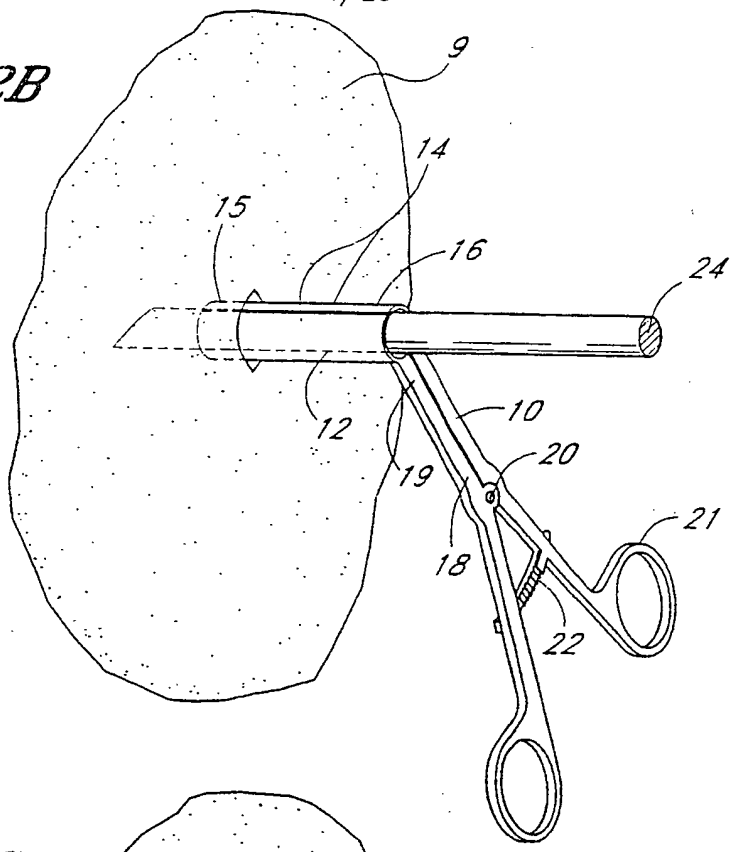

Fig. 2C

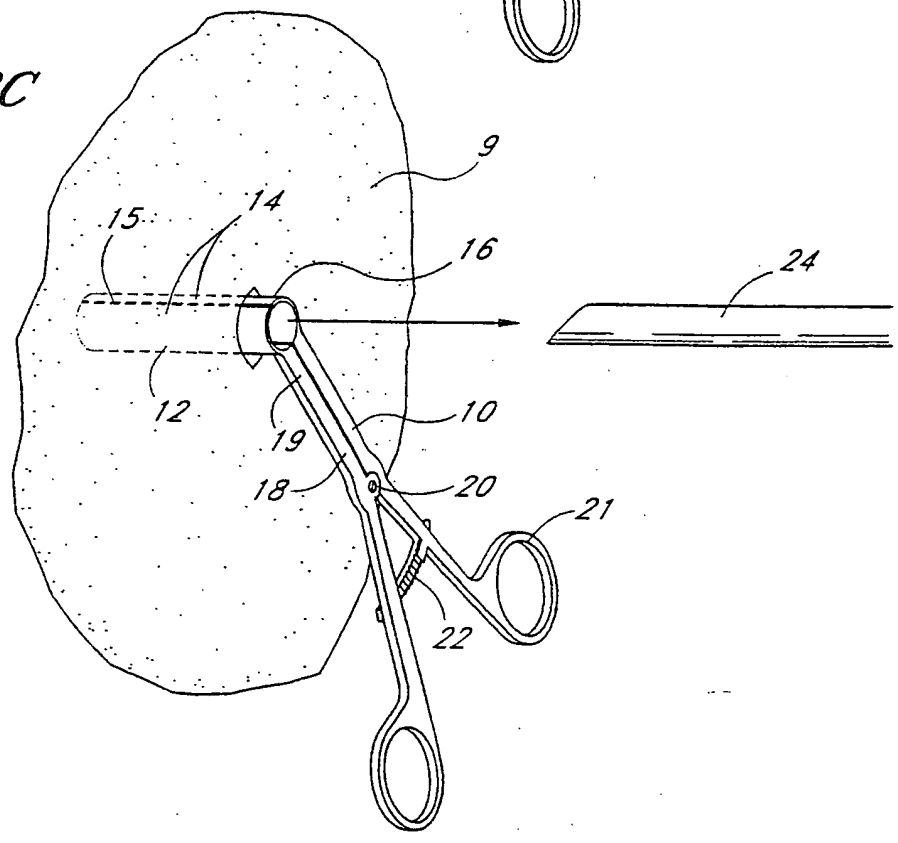

Fig. 2F

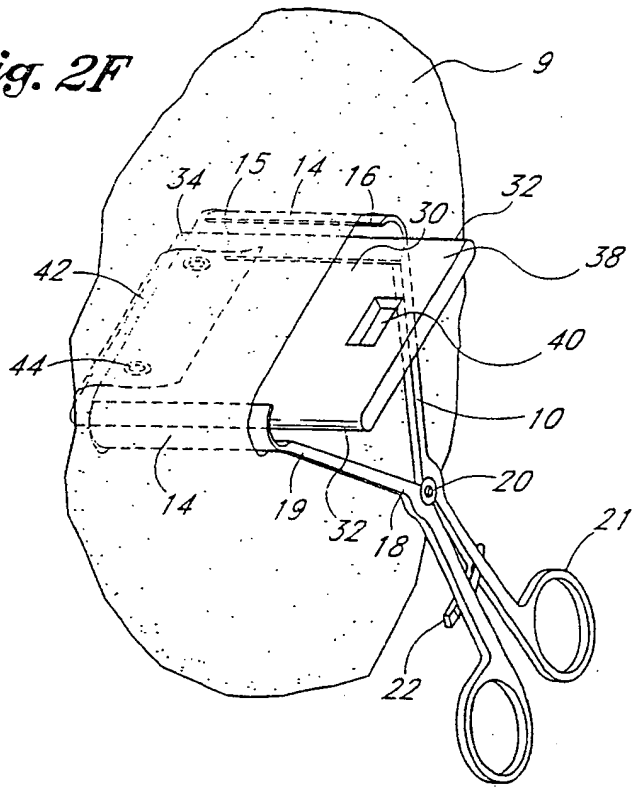
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Fig. 2G

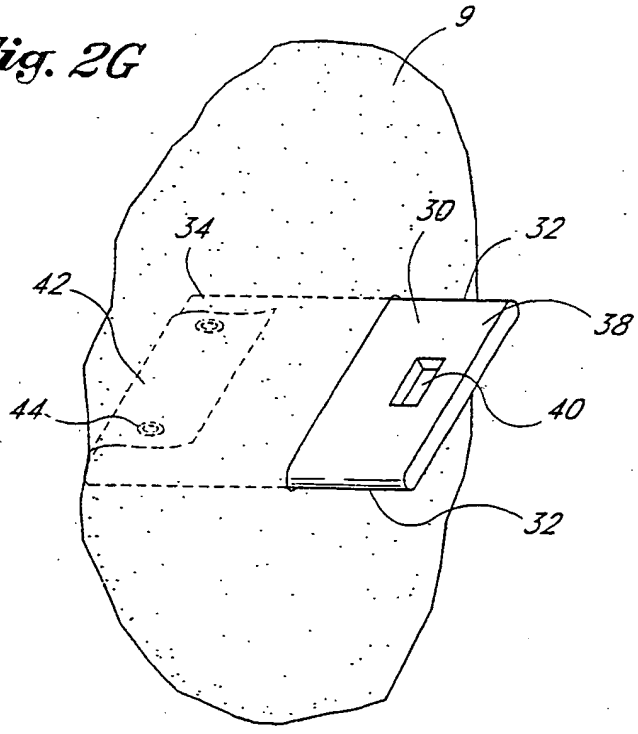
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Fig. 6A

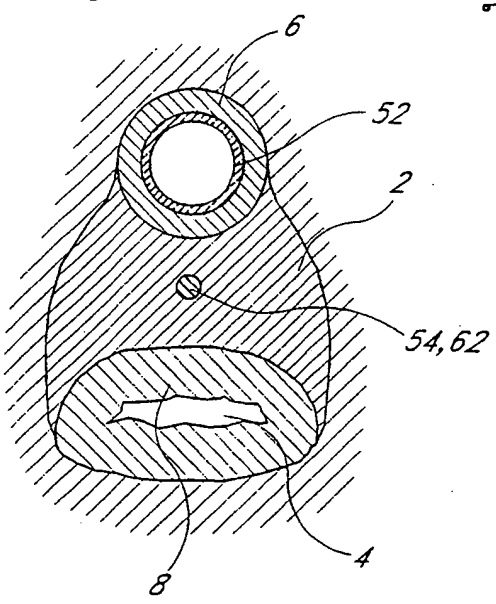
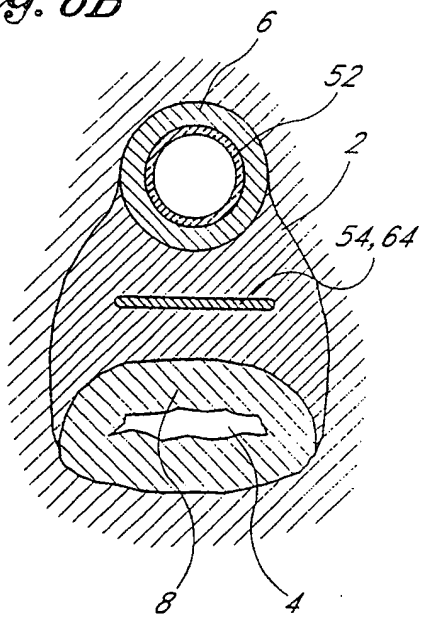


Fig. 6B



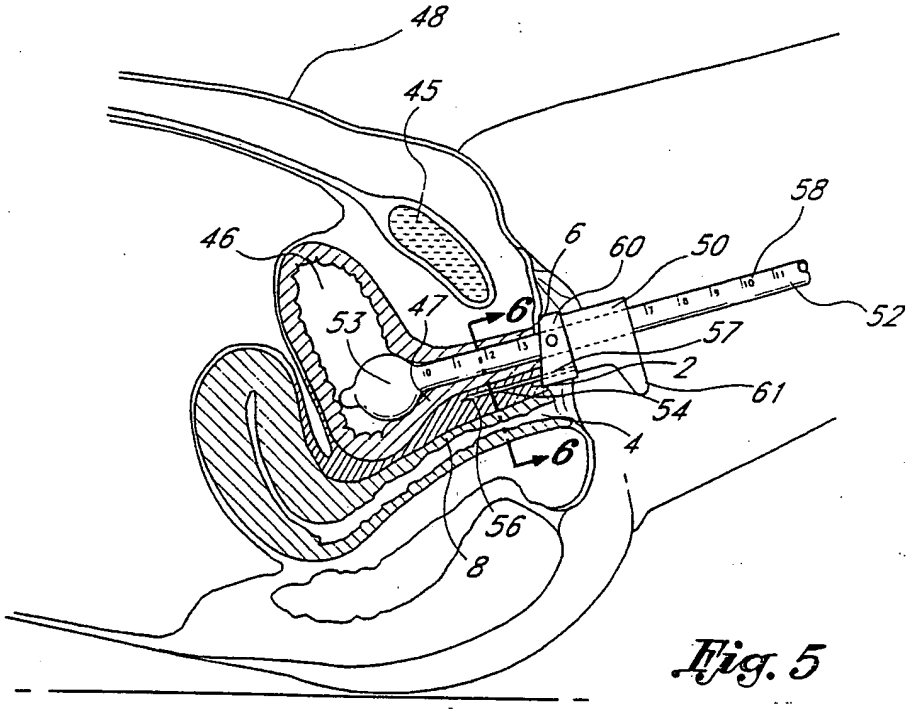


Fig. 5

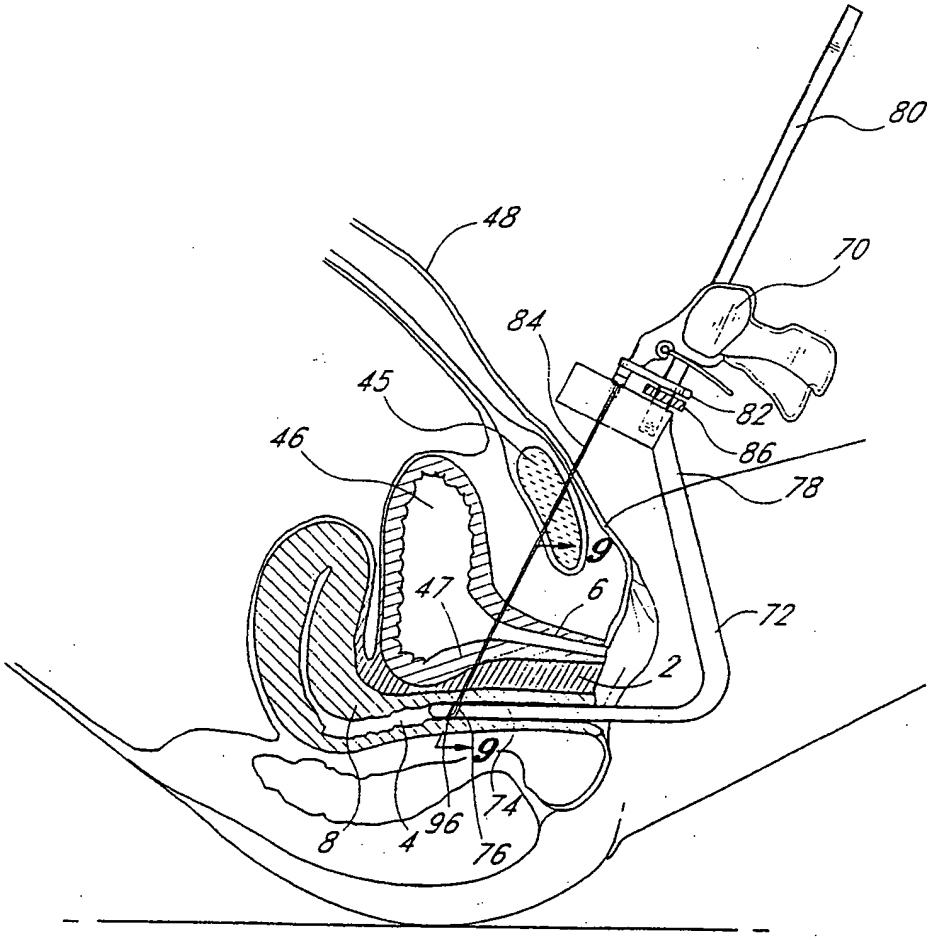


Fig. 8

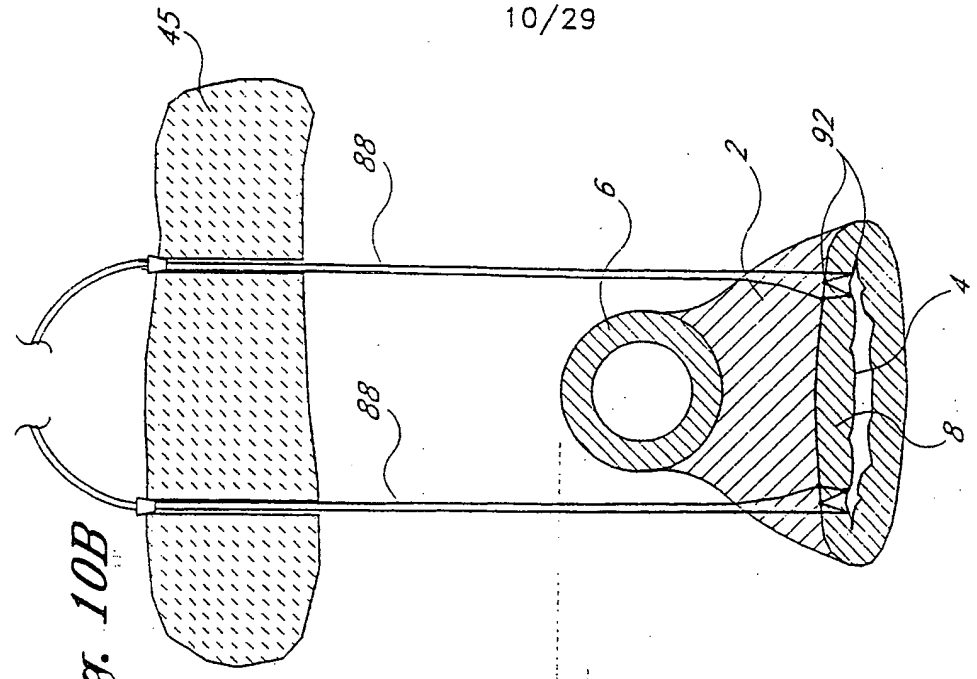


Fig. 10B

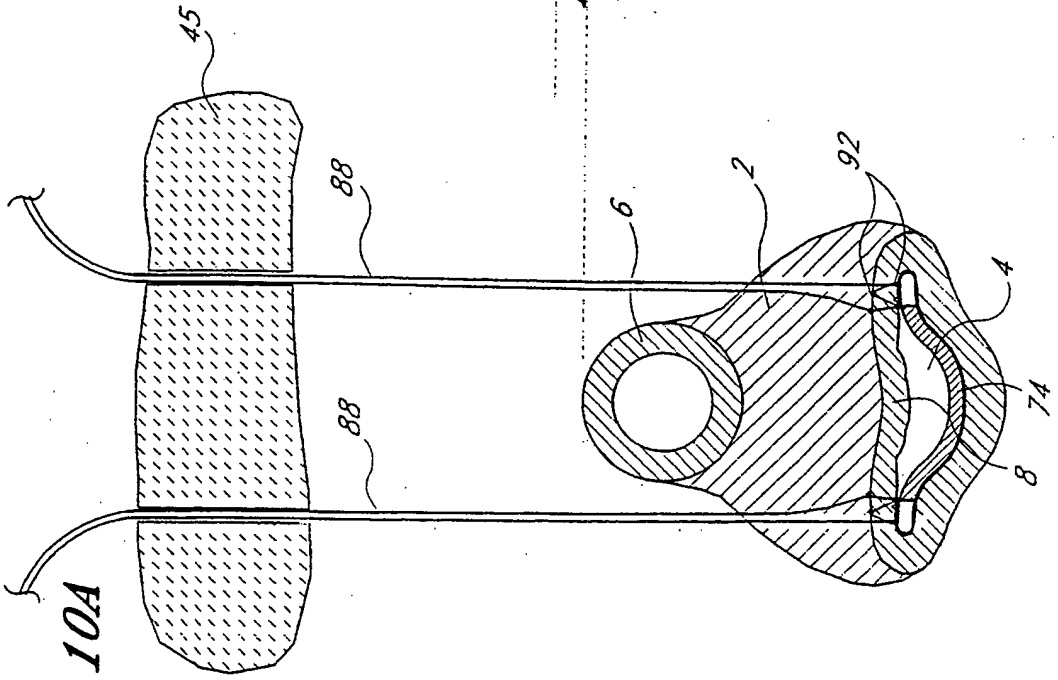


Fig. 10A

Fig. 12b

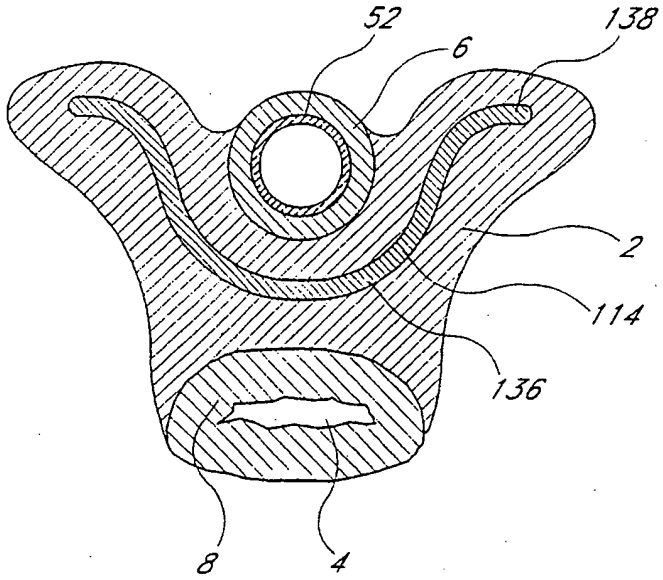


Fig. 12c

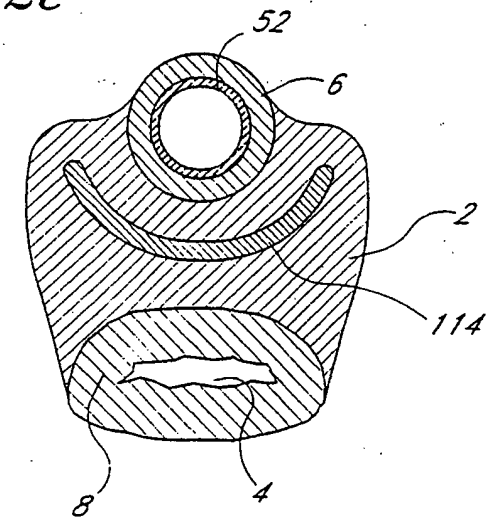


Fig. 16

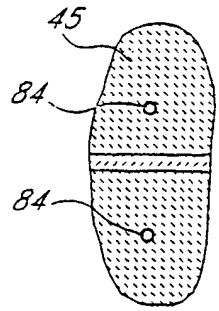

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Fig. 15

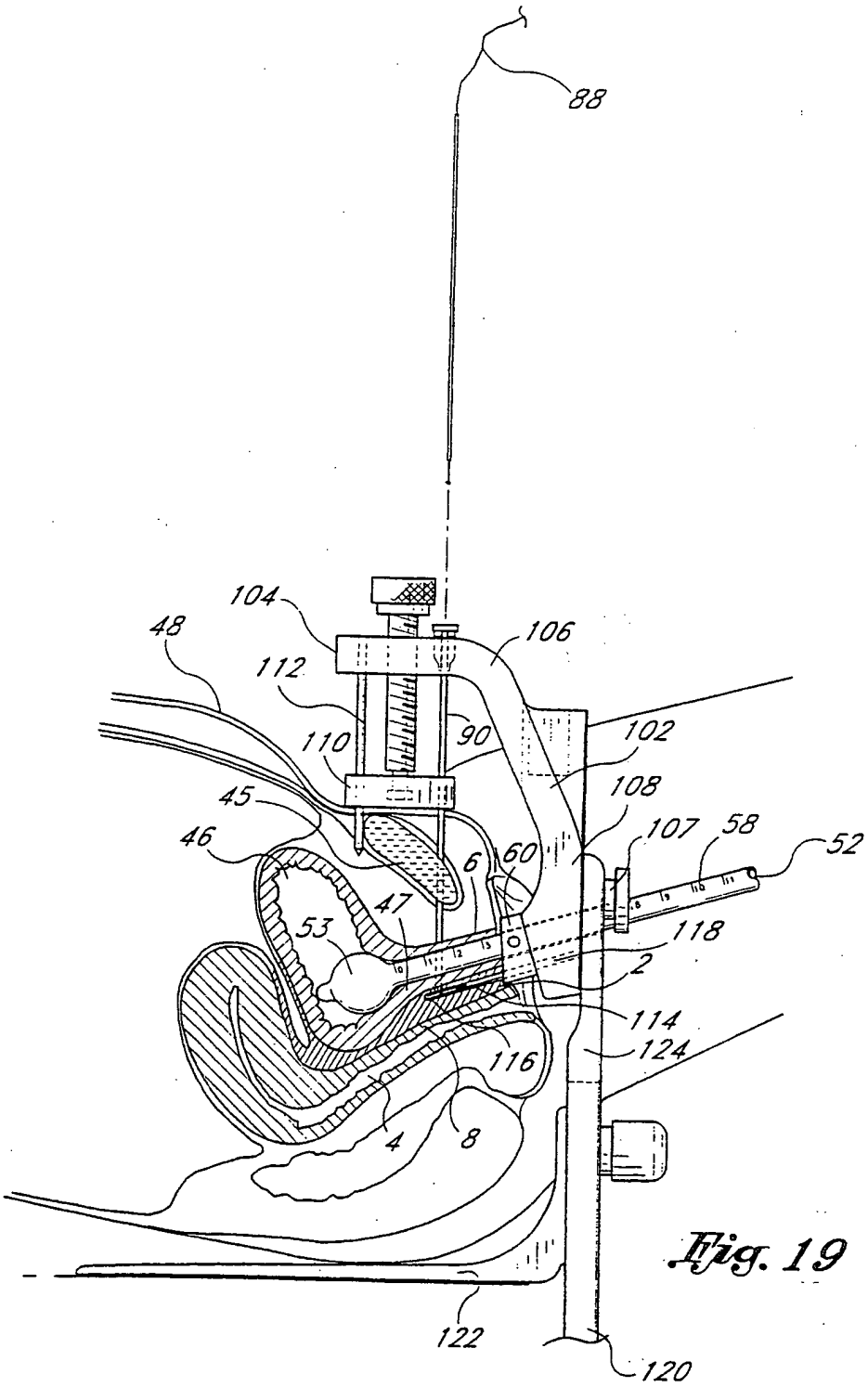
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Fig. 19

Fig. 21

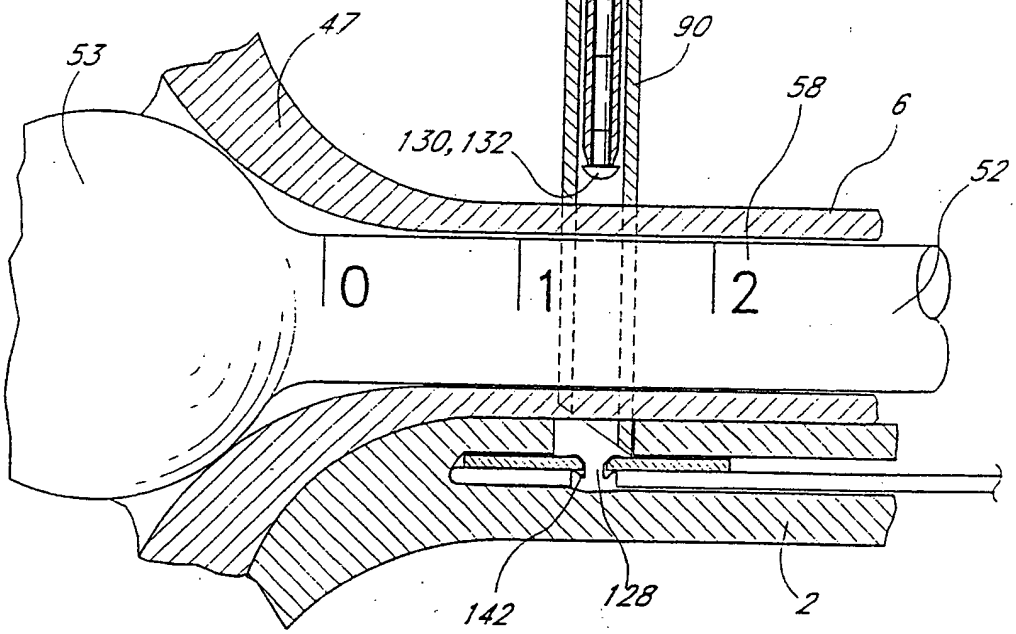
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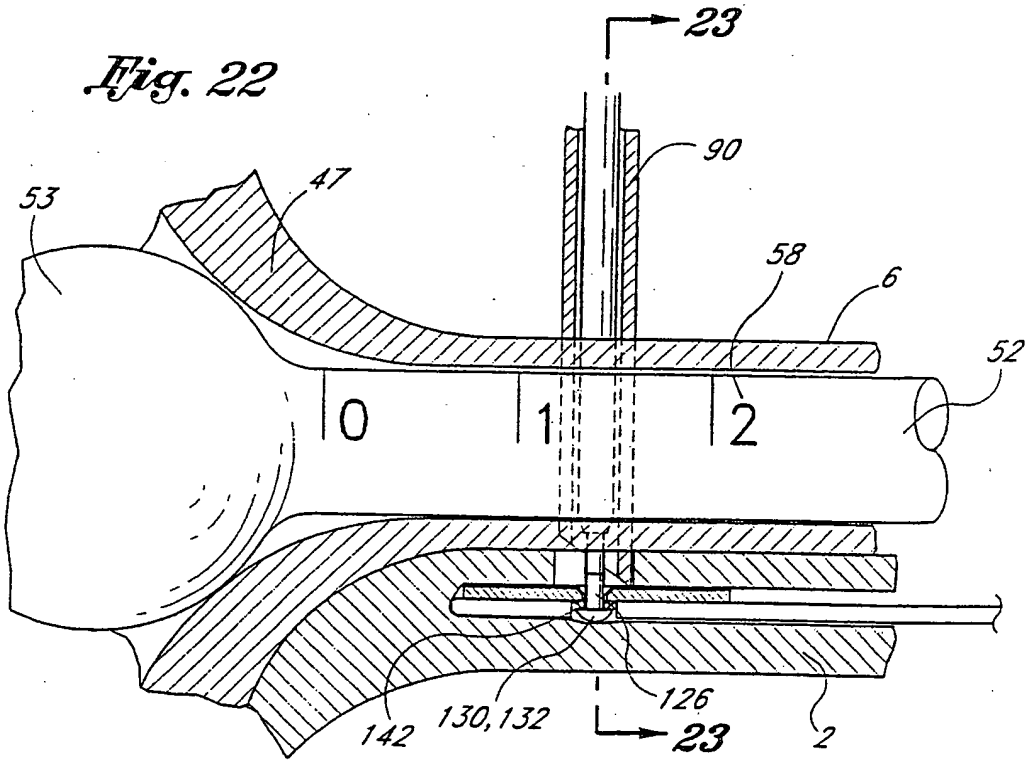
Fig. 22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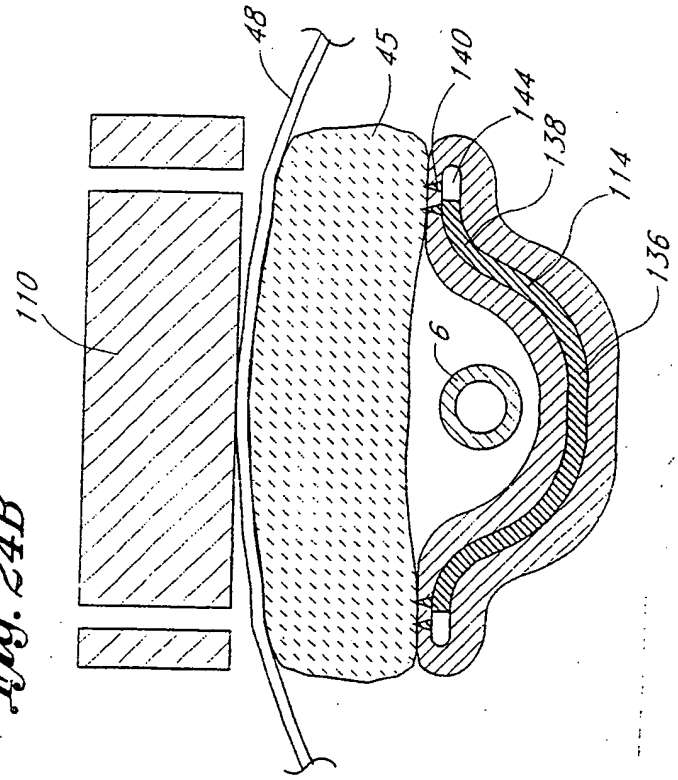


Fig. 24B

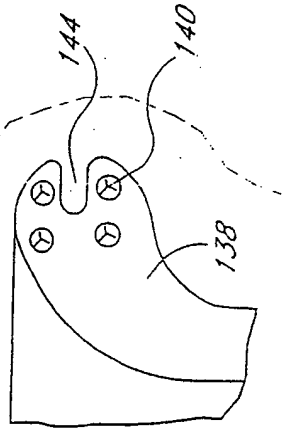


Fig. 25

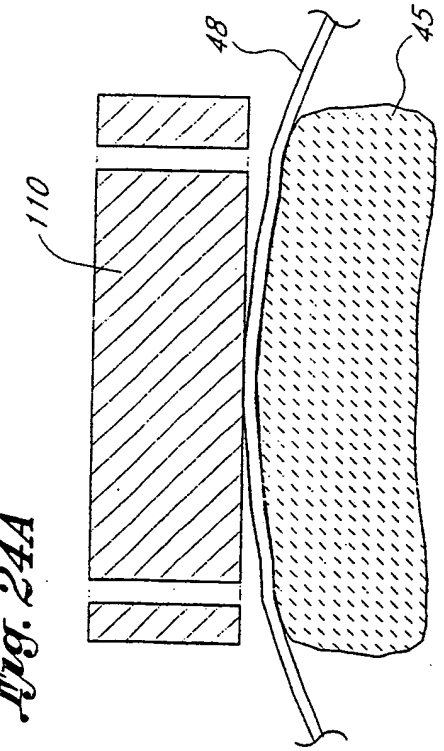
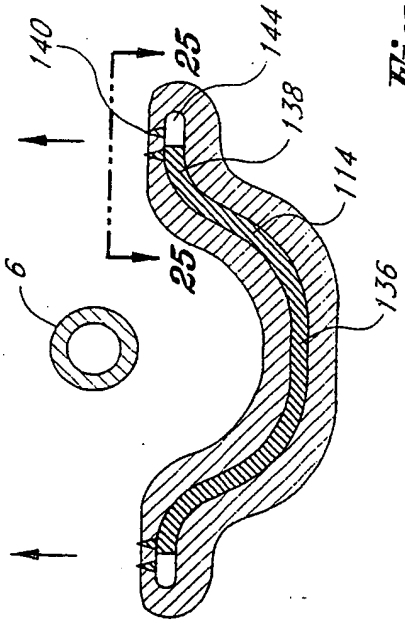


Fig. 24A



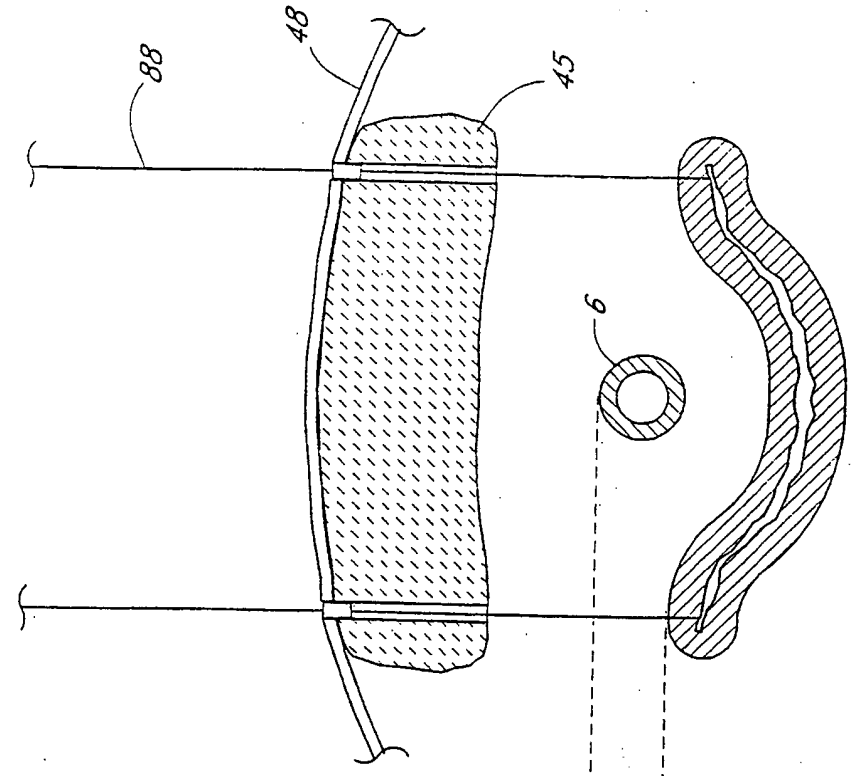


Fig. 27B

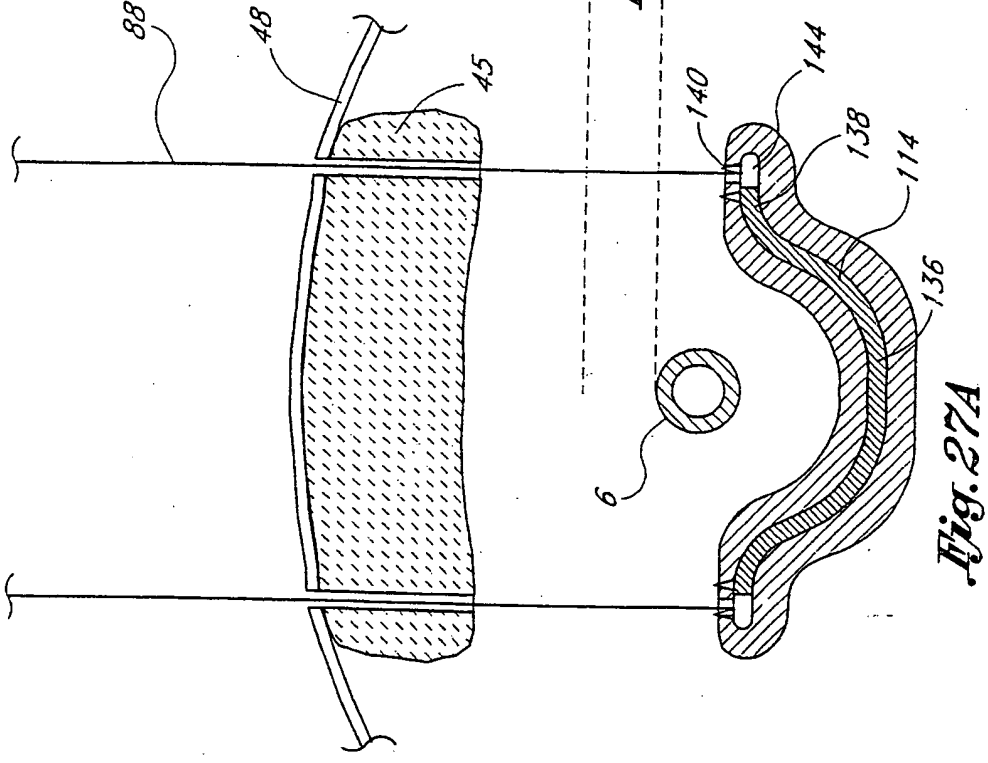


Fig. 27A

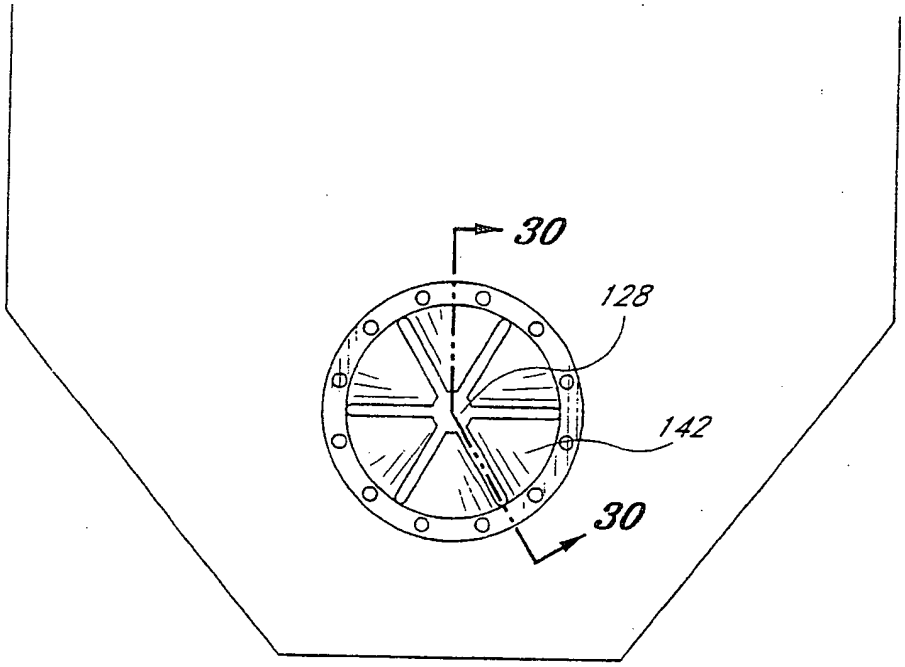


Fig. 29

Fig. 30

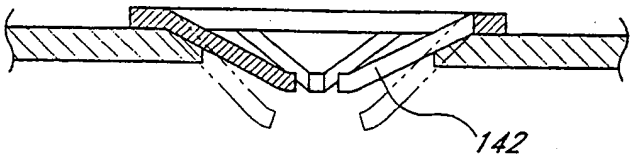


Fig. 33

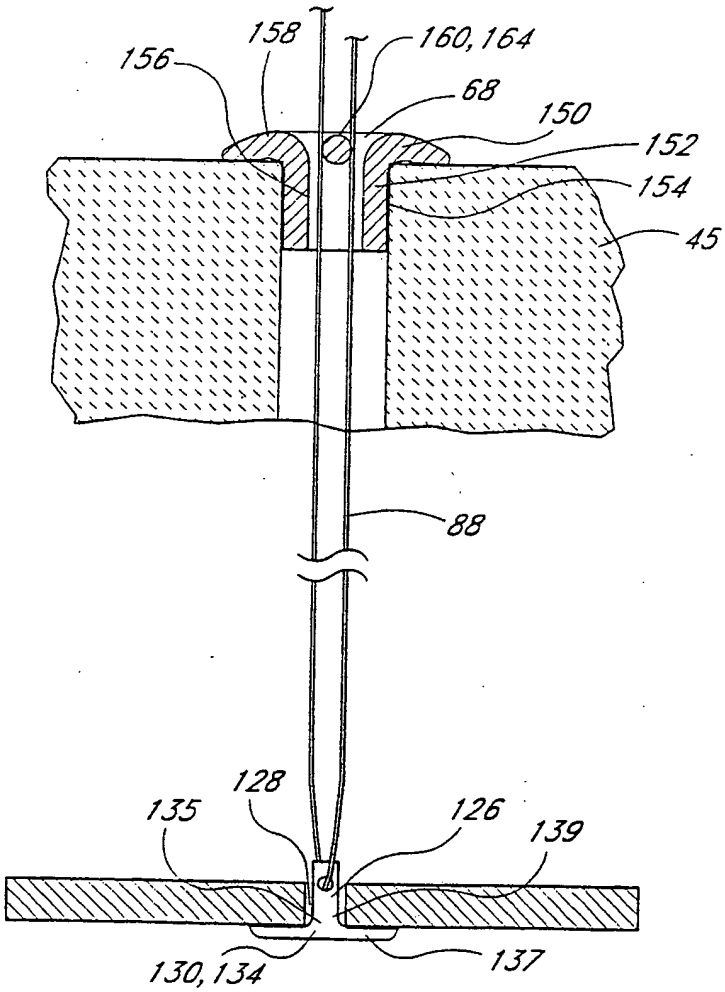


Fig. 36

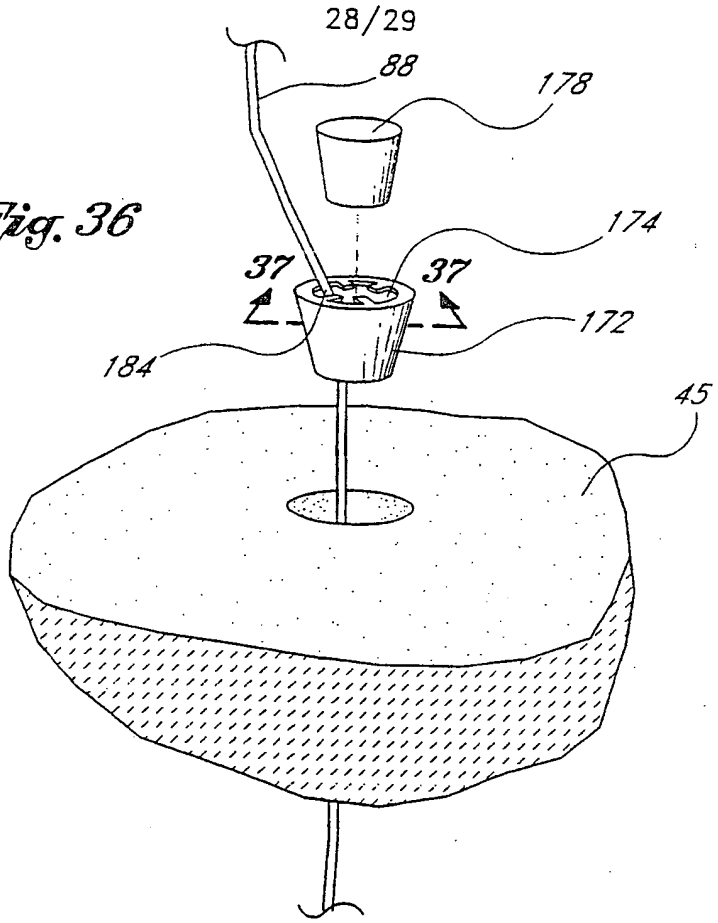
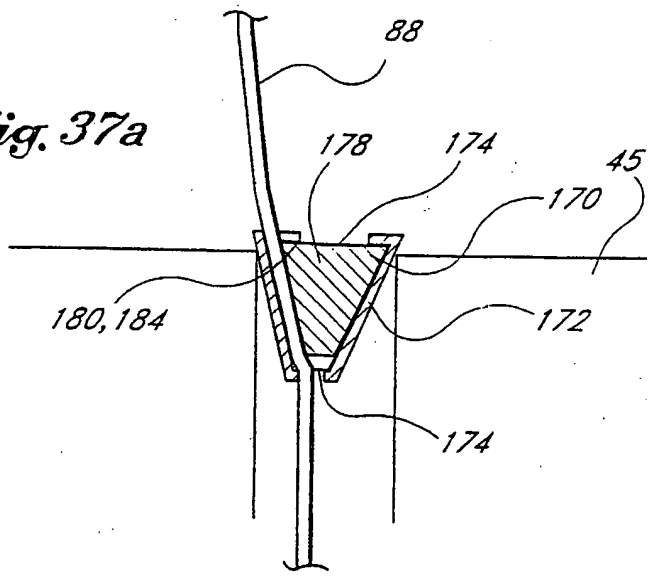


Fig. 37a



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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/04 — A3

(11) International Publication Number: WO 98/35606

(43) International Publication Date: 20 August 1998 (20.08.98)

(21) International Application Number: PCT/US98/03069

(22) International Filing Date: 13 February 1998 (13.02.98)

(30) Priority Data:
60/038,380 13 February 1997 (13.02.97) US

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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

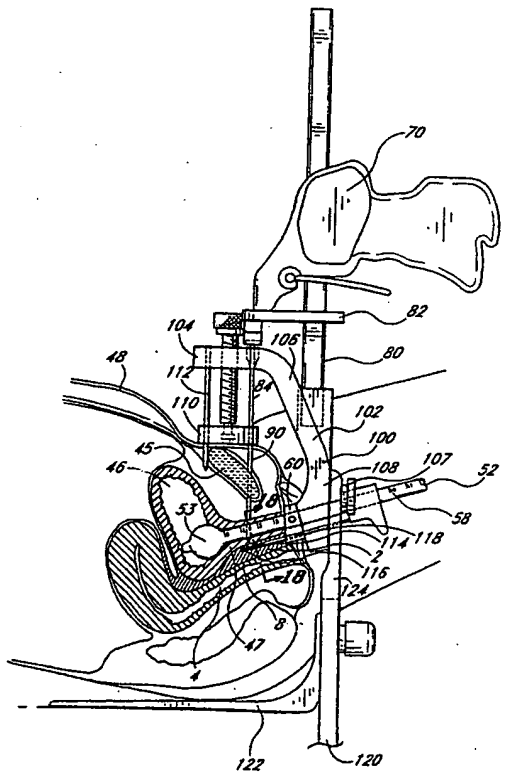
With international search report.

(88) Date of publication of the international search report:
10 December 1998 (10.12.98)

(54) Title: METHOD AND APPARATUS FOR MINIMALLY INVASIVE PELVIC SURGERY

(57) Abstract

The invention provides a driver (70) and methods for advancing needles, cannulas (90), and other medical devices through the pubic bone (45). The driver (70) may be used in connection with a driver frame assembly (100) for proper positioning and stabilization of the driver (70), and with other devices for creating a cavity in the urethral floor and for positioning medical devices therein. The invention also provides simple connections (126) for attaching a suture (88) to a device within the cavity in the urethral floor or in the vagina (4), and also for attaching sutures (88) to the pubic bone (45).



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/03069

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/04

US CL :128/898; 600/29, 30, 222; 606/72, 139, 190, 198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 600/29, 30, 222; 606/72, 139, 190, 198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,569,300 A (REDMON) 29 October 1996, col. 4 lines 7-62.	1
X	SU 610,512 A ((LENSKII) 15 June 1978, Abstract.	1
A	US 5,562,679 A (VALTCHEV) 08 October 1996, col. 1 lineS 35-66, and col. 2 lines 1-4.	22-38
A	US A 3,580,313 A (McKNIGHT) 25 May 1971, entire document.	22-38

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

13 JULY 1998

Date of mailing of the international search report

13 AUG 1998

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Telephone No. (703) 308-4302

Form PCT/ISA/210 (second sheet)(July 1992)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/03069

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-3, drawn to a dilator.

Group II, claims 4-9, drawn to a method of creating a cavity in tissue.

Group III, claims 10-13, drawn to a system for inserting a device into tissue (card), and a method for advancing a card into tissue.

Group IV, claims 14-19 and 20, drawn to an incision guide for creating a cavity, and a method of creating a cavity in a vaginal hiatus.

Group V, claim 21, drawn to a method of advancing a sling. into a cavity into a tissue cavity.

Group VI, claims 22-38, drawn to a driver for driving a guide into a pubic bone, and method of using the same.

Group VII, claims 39 and 40, drawn to a method of pelvic surgery.

Group VIII, claim 41, drawn to a method of stabilizing a urethral sling to a pubic bone.

Group IX, claims 42 and 43, drawn to a driver frame assembly.

Group X, claim 44, drawn to a system for attaching a urethral sling to a suture.

Group XI, claim 45, drawn to a bone eyelet.

Group XII, claim 46, drawn to a quick connect bone suture fastener.

Groups II-XII, the inventions listed as these groups do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same, or corresponding special technical features.